

person interview on March 1, 1999. Richard Wisniewski, David Abraham, Examiner Chandler, and Supervisory Primary Examiner Lazarus were present during the interview. During the interview, Mr. Wisniewski discussed the background of the technology surrounding the present invention. Following this, there was a general discussion of the claim terminology, together with a comparison of the cited references against the claimed invention. While no agreement was reached, Examiner Chandler, and Supervisory Primary Examiner Lazarus did agree to carefully consider any claim amendments and arguments submitted as part of a Response to the outstanding Office Action.

Objection by Examiner to Patent Drawings:

Applicants note that the drawings have been objected to by the Examiner. Applicants respectfully request that the Office provide guidance as to the nature of the objection. At that point, Applicants will address the Office's grounds for the objection.

Claim for Priority under 35 U.S.C. § 119(e):

Applicants note that the Office indicates an acknowledgement of a claim for domestic priority under 35 U.S.C. § 119(e). Applicants do not, at the present time, claim such priority. Applicants therefore respectfully request that the Office provide guidance as to the nature of the acknowledgement.

Rejections under 35 U.S.C. § 103(a):

The Office rejects claims 1-5, 9, 10, 14-20, 22-30, and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lundvall et al. (U. S. Patent No. 2,610,034). Applicants traverse this rejection.

Amended independent claim 1, and claims 2-5, 9, 10, 14-20, 22-30, and 33, which depend from claim 1, require that "the medium [comprises] a biopharmaceutical

product." As the Office itself notes, "[t]he only limitations not disclosed by Masel are as follows: a biopharmaceutical product serving as the medium." (Office Action at 5, lines 6-7.) Applicants agree with the Office that Masel fails to disclose mediums comprising biopharmaceutical products. Lundvall et al. is directed to milk cooling attachments for milking machines. Conventional raw milk is not a biopharmaceutical product. Lundvall et al. contains no other discussion of biopharmaceutical products. Consequently, Lundvall et al. does not make up for the deficiencies of Masel.

The combination of the cited references fails to teach or suggest all of the claim limitations. Accordingly, a proper *prima facie* case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the withdrawal of the rejection of claims 1-5, 9, 10, 14-20, 22-30, and 33 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lundvall et al. (U. S. Patent No. 2,610,034).

The Office rejects claims 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lundvall et al. (U. S. Patent No. 2,610,034), further in view of Allo (U.S. Patent No. 4,296,612). Applicants traverse this rejection.

Claims 6-8 depend from amended independent claim 1. As such, they require that "the medium [comprises] a biopharmaceutical product." As noted above, Masel in view of Lundvall et al. fail to teach or suggest this claim limitation. Allo does not rectify the deficiencies of Masel in view of Lundvall et al. Allo is directed to freeze exchangers for concentrating a liquid mixture containing dissolved or suspended solids. There is no teaching or suggestion that the liquid mixture of Allo may be a medium comprising a biopharmaceutical product.

The combination of the cited references fails to teach or suggest all of the claim limitations. Accordingly, a proper *prima facie* case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the withdrawal of the rejection of

claims 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lundvall et al. (U. S. Patent No. 2,610,034), further in view of Allo (U.S. Patent No. 4,296,612).

The Office rejects claims 11 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Mekjean (U.S. Patent No. 3,453,416). Applicants traverse this rejection.

Claims 11 and 31 depend from amended independent claim 1. As such, the claims require that “the medium [comprises] a biopharmaceutical product.” As noted above, Masel fails to teach or suggest this claim limitation. Mekjean does not rectify the deficiencies of Masel. Mekjean is directed to electric heaters utilized in heat a heat storage medium. There is no teaching or suggestion that the heat storage medium of Mekjean may be a medium comprising a biopharmaceutical product.

The combination of the cited references fails to teach or suggest all of the claim limitations. Accordingly, a proper *prima facie* case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the withdrawal of the rejection of claims 11 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Mekjean (U.S. Patent No. 3,453,416).

The Office rejects claims 21, and 35 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lindemans (U.S. Patent No. 4,712,607.). Applicants traverse this rejection.

First, Applicants note that claim 21 has been cancelled, making its rejection moot. Claim 35, which depends from independent amended claim 1, requires that a portion of said first heat exchange member is placed in close proximity to a portion of said second heat exchange member.

The Office points to a removable freezing cartridge disclosed by Masel (FIG. 1a) and argues that this includes “a container (3), a structure in the container (4), and a

heat exchange member (16a) at least partially coupled to interior surface, and a distal end of the heat exchange member in close proximity to the structure.” (Office Action at page 5, lines 2-6). The Office additionally argues that it would have been obvious to “modify the heat transfer system of Masel to include the biopharmaceutical medium of Lindemans for the purpose of quickly freezing and thawing the medium.” (Office Action at page 5, lines 9-12.)

Applicants point out that one of ordinary skill would not be motivated to make such a combination because the resulting combination would be useless.

The medium contained within the freezing cartridge of Masel is a phase-changing material having a melting point lower than the freezing point of the liquid to be frozen. (Masel at col. 3, lines 25-27.) An example of such a liquid is disclosed as ethylene glycol. Completely replacing the ethylene glycol of Masel with a biopharmaceutical medium would have rendered the entire apparatus inoperable – there would be nothing to freeze or thaw the medium because the source of cooling (ethylene glycol) would be gone. Introducing a mixture of ethylene glycol and a biopharmaceutical medium into the freezing cartridge of Masel would have contaminated the biopharmaceutical medium. There would be no expectation of successfully combining the teachings of the references, because the combination would render useless the biopharmaceutical product.

There is no suggestion or motivation to combine the cited references. Consequently, no *prima facie* case of obviousness has been made out. MPEP

§ 2143.01. For all of the above reasons, applicants request the withdrawal of the rejection of claims 21 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Masel (U.S. Patent No. 4,793,151) in view of Lindemans (U.S. Patent No. 4,712,607.).

The Office rejects claims 12, 32, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Joshi (U.S. Patent No. 4,893,670) in view of Henderson (3,934,618). Applicants traverse this rejection.

Claims 12, 32, and 34 depend from amended independent claim 1. As such, they require that “the medium [comprises] a biopharmaceutical product.” Joshi is directed to oil coolers for automotive applications. Henderson is directed to jacketed pipe assemblies for containing molten polymers. There is no teaching or suggestion either that the oil of Joshi or the molten polymers of Henderson may be a medium comprising a biopharmaceutical product.

The combination of the cited references fails to teach or suggest all of the claim limitations. Accordingly, a proper *prima facie* case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the withdrawal of the rejection of claims 12, 32, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Joshi (U.S. Patent No. 4,893,670) in view of Henderson (3,934,618).

Allowable Subject Matter

The Office has indicated that claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent from including all of the limitations of the base claim and any intervening claims. Applicants appreciate the indication of allowability.

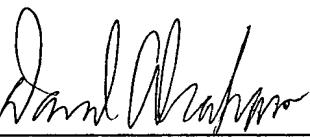
Conclusion:

Applicants submit that currently pending claims 1-20, and 22-35 are in condition for allowance. Prompt consideration and timely issuance of all pending claims is respectfully requested. Any questions regarding this matter may be addressed to the undersigned at (650) 849-3438.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By:



David J. Abraham
Registration No. 39,554

650 Page Mill Road
Palo Alto, California 94304-1050
Telephone: (650) 493-9300
Date: 3/19/99